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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,627	08/03/2001	Arthur E. Colvin JR.	2232-146	8027

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EXAMINER
COLE, MONIQUE T

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,627	COLVIN, ARTHUR E.	
	Examiner	Art Unit	
	Monique T. Cole	1743	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46,48-53 and 55-58* is/are rejected.

7)☒ Claim(s) *47,54 and 59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-4, 10-12, 14-17, 23-25, 27-30, 36-38, 41-44, 48-51, 55 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,002,954 to Van Antwerp et al. (herein referred to as "Van Antwerp '954").

Van Antwerp '954 disclose a method for the determination of the concentration of glucose which comprises immobilizing an anthracene derivative, such as 9-((N-Methyl-N-(o-boronobenzyl)amino)methyl) anthracene, within a hydrophilic polymer (one or more hydrophilic monomers) matrix (col. 12, lines 22-23). See abstract; col. 11, lines 35-41; col. 12, lines 22-24; col. 18, lines 9-10. Anthracene compounds inherently possess excimer-forming capabilities. The method is capable of being used in an aqueous environment, such as that found in the blood (col. 4, lines 50-53).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 7, 20 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Antwerp '954.

Van Antwerp '954 fails to explicitly teach that the ratio of the hydrophilic monomer to the indicator component is from about 2:1 to about 1000:1. However, where the general conditions of a claim are taught in the prior art, it is not inventive to discover the optimum or workable ranges. It would have been obvious to one having ordinary skill in the art to modify the ratio of the hydrophilic monomer to the indicator component in order to adjust the strength of the signal produced by the indicator.

5. Claims 1, 2, 6, 10, 11, 12, 14, 15, 19, 23-25, 27, 28, 32 and 36-38 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,344,360 to Colvin et al. (herein referred to as "Colvin '360").

Colvin '360 discloses compositions and methods for determining the presence or concentration of glucose by exposing the sample to an indicator molecule comprising a fluorescent lanthanide metal chelate complex. The presence or concentration of glucose in the sample is determined by observing and/or measuring the change in intensity of fluorescence emitted by the lanthanide metal chelate complex. See abstract. The lanthanide metal chelate complex can be used in an aqueous environment, such as that found in blood or urine (col. 15, lines 47-50).

Colvin '360 differs from the instantly claimed invention because it does not describe the lanthanide metal chelate complex in terms of its individual components. Namely, it does not explicitly disclose that the complex comprises both an hydrophobic indicator component monomer and a hydrophilic monomer. However, the indicator component monomer in Colvin '360 is a lanthanide chelate, which is insufficiently water soluble to permit its use in an aqueous environment. Since then the complex of Colvin '360 can be utilized in aqueous environments (blood, urine), one of ordinary skill in the art may then infer that the lanthanide chelate is in some way chemically manipulated to render it hydrophilic and thus useful in the aforementioned aqueous environments. Thus, it would have been obvious to one of ordinary skill in the art to describe the complex in terms of its hydrophobic and hydrophilic components.

6. Claims 7, 20 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin '360.

With regard to the ratio of the hydrophilic monomer to the indicator component, Colvin '360 fails to explicitly teach that it is from about 2:1 to about 1000:1. However, where the general conditions of a claim are taught in the prior art, it is not inventive to discover the optimum or workable ranges. It would have been obvious to one having ordinary skill in the art to modify the ratio of the hydrophilic monomer to the lanthanide chelate to increase its hydrophilicity. One of ordinary skill in the art would recognize the necessity of modifying these components in order to facilitate the reception of the lanthanide chelate into the aqueous environment.

7. Claims 3, 4, 16, 17, 29, 30, 41-44, 48-51, 53, 55, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin '360 as applied to claims 1, 2, 6, 10, 11, 12, 14, 15, 19, 23-25, 27, 28, 32 and 36-38 above, and further in view of Van Antwerp '954.

Colvin '360 fails to teach that the indicator component monomer comprises an N-(o-boronobenzyl) amino)methyl) anthracene derivative. However, Van Antwerp '954 teach this particular excimer-forming, indicator component monomer for use in detecting glucose in an aqueous environment. Thus because the indicator component monomer taught by Van Antwerp '954 is used in a manner similar to that of Colvin '360, it would have been obvious to one of ordinary skill in the art to modify the Colvin '360 reference by using a N-(o-boronobenzyl) amino)methyl) anthracene derivative, such as taught by Van Antwerp '954, with the expectation of obtaining suitable detection capabilities.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1, 3, 5, 6, 8, 9, 11, 12, 13, 14, 16, 18, 19, 21, 22, 24, 25, 26, 27, 29, 31, 32, 34, 35, 37, 38, 39-46, 48-53, and 55-58 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 7, 9, 10, 11-15, 17, 18, 20-26, 28, 29, 31 and 32-50 of copending Application No. 09/632,624. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 2, 4, 7, 10, 15, 17, 20, 23, 28, 30, 33 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-10, 12, 16-21, 23 and 27-32 of copending Application No. 09/632,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because with regard to the ratio of the hydrophilic monomer to the indicator component monomer, these claims cover the same ranges. Further, although the claims of 09/632,624 do not recite that there

is an optical change that is detected, it would have been obvious to one of ordinary skill in the art that optical change is the parameter used to determine a change in the presence or concentration of the analyte with the claimed indicator, which is a known fluorescent indicator. Also, while it is noted that Applicant has listed particular anthracene derivatives in the instant application, all of these compounds would have been within the scope of the previous claims and would have been obvious based on the recognition by the 09/632,624 that such compounds are suitable indicator component monomers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1, 2, 6, 10, 11, 12, 14, 15, 19, 23-25, 27, 28, 32 and 36-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-18 of Colvin '360. Although the conflicting claims are not identical, they are not patentably distinct from each other because although Colvin '360 does not explicitly disclose the lathanide metal chelate complex in terms of hydrophobicity/hydrophilicity, the complex is embraced by the instant claims. In Colvin, the indicator component that is individually not sufficiently water soluble to be used in an aqueous environment is used to detect blood glucose (aqueous environment).

Allowable Subject Matter

13. Claims 47, 54 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest using (3-(methacryloylamino)-propyl)trimethylammonium chloride as the hydrophilic monomer in an indicator macromolecule for the detection of analytes in aqueous environments. The prior art does not teach or suggest a molar ratio of hydrophilic monomer to indicator component monomer from about 5:1 to about 50:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole
Examiner
Art Unit 1743

MC MC
July 26, 2002

Jill Warden
Supervisory Patent Examiner
Technology Center 1700